



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1580]

Patient Preference Information--Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Device Labeling; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Patient Preference Information--Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling." This document provides guidance on collecting and submitting patient preference information that may be used by FDA staff in decisionmaking relating to premarket approval applications (PMAs), Humanitarian Device Exemption (HDE) applications, and de novo requests. This draft guidance also outlines considerations for including patient preference information in labeling for patients and health care professionals. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on

the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Patient Preference Information--Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Anindita Saha, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5414, Silver Spring, MD 20993-0002, 301-796-2537, Anindita.Saha@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Patient Preference Information--Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling." FDA believes that patients can and should bring their own experiences to bear in helping the Agency to evaluate the risk-benefit profile of certain devices. This document provides guidance on collecting and submitting patient preference information that may be used by FDA staff in decision-making relating to PMAs, HDE applications, and de novo requests. The objectives of this draft guidance are: (1) To encourage voluntary submission of patient preference information by sponsors or other stakeholders in certain circumstances; (2) to outline recommended qualities of patient preference studies, which may result in valid scientific evidence; (3) to provide recommendations for collecting and submitting patient preference information to FDA; and (4) to outline considerations for including patient preference information in labeling for patients and health care professionals. This draft guidance includes examples that illustrate how patient preference information may inform FDA's regulatory decisionmaking. The guidance applies to both diagnostic and therapeutic devices that are subject to these review processes. Additionally, this guidance may apply to other stakeholders such as patient groups and academia who may wish to conduct patient preference studies.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Patient Preference Information--Submission, Review in PMAs, HDE

Applications, and De Novo Requests, and Inclusion in Device Labeling. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from CBER at

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Persons unable to download an electronic copy of "Patient Preference Information--

Submission, Review in PMAs, HDE Applications, and De Novo Requests, and Inclusion in Device Labeling" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500006 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 812.25(c) have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814 subparts B and E have been approved under OMB control number 0910-0231; the collections of

information in 21 CFR part 814 subpart H have been approved under OMB control number 0910-0332; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Specifically the Agency would like comments on the following questions:

1. Section IV of the draft guidance recommends qualities for patient preference studies. Do you believe these recommended qualities are clear and understandable? If not, what should be reworded or edited? Is there anything missing? If so, what needs to be added?
2. Under what conditions should health care professional or patient labeling include information about patient preference studies?
3. How should sponsors present patient preference information in the health care professional and patient labeling?
4. How should labeling indicate that only a subset of patients in a patient preference study were willing to accept certain risks in order to achieve probable benefits?
5. How should sponsors and the FDA ensure that patients receive and understand patient preference information?

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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